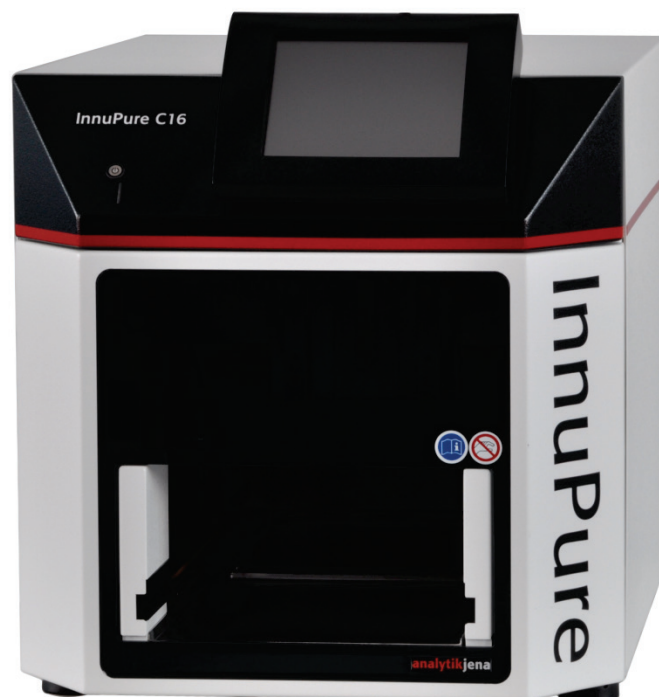


InnuPure C16

Extraction system



Operating manual

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1 Basic Information

1.1 User manual notes

The InnuPure C16 is intended for operation by qualified specialist personnel observing this user manual.

The user manual informs about the design and operation of the InnuPure C16 and provides personnel familiar with the isolation and purification of nucleic acid the necessary know-how for the safe handling of the equipment and its components. The user manual further includes notes on the maintenance and service of the equipment and potential causes and remedies of any faults.

User manual conventions

Instructions for action which occur in chronological order are numbered and combined into action units and furnished with the corresponding results.

Lists which are not in chronological order are shown as itemized lists, sub-listings as bullet points.

Safety notes are indicated by pictographs and signal words. The type and source of the danger are stated together with notes on preventing the danger. The meaning of the pictographs and signal words used is explained in the chapter "Safety notes".

The elements of the control program are indicated as follows:

- ☐ Program terms are identified with SMALL CAPS.
- ☐ Buttons are shown by square brackets (e.g. [OK] button)
- ☐ Menu items are divided by an upright line (e.g. FILE | OPEN).

1.2 Intended use

The InnuPure C16 is a flexible and efficient extraction system for the fully automated isolation and purification of nucleic acid in chemical and biological laboratories. In the field of medicine and diagnostics its use is limited to research.

The InnuPure C16 including its original accessories must only be used for the applications described in this instruction manual. The manufacturer does not accept liability for any other use, including that of any individual modules or components.

- ☐ The device must only be operated by qualified and trained personnel.
- ☐ The device must only be used in accordance with this instruction manual. This applies in particular to the adherence to the connection values, conditions of use and notes on maintenance, service, transport and disposal.
- ☐ The safety notices in this instruction manual must be observed.

It is not permissible,

- ☐ to work with explosive substances in this device
- ☐ to operate this device in an explosive environment
- ☐ to use consumables that are not recommended for the InnuPure C16 and the corresponding kits
- ☐ to use overfilled consumables.

The operator is responsible for the use of the equipment as intended.

1.3 Warranty and liability

The warranty duration and liability comply with the legal requirements and the provisions in the general terms and conditions of Analytik Jena AG.

Deviations from the intended use described in this user manual result in limitations of warranty and liability during a damage event. Damage to wearing parts is not included in the warranty.

Warranty and liability claims are excluded for personal injury and property damage due to one or several of the following causes:

- ☐ use of the InnuPure C16 other than intended
- ☐ improper commissioning, operation and service of the device
- ☐ modifications of the equipment without prior consultation with Analytik Jena AG
- ☐ unauthorized intervention in the equipment
- ☐ operation of the device with faulty safety equipment or improperly fitted safety and protection equipment
- ☐ inadequate monitoring of the equipment components subject to wear
- ☐ use of other than original spare parts, wearing parts or consumables
- ☐ improper repairs
- ☐ faults due to the non-observance of this user manual

2 Technical data

System parameters	
Extraction principle	based on surface-functionalized magnetic or paramagnetic particles
Extraction duration	from 45 min (dependent on the source material)
Drive	5 low-noise long-life servomotors
Device operation	stand-alone via HID-Pro 320 with 5.7" touchscreen (color)
Maintenance	maintenance-free through the use of non-wearing stainless steel pistons
Cleaning	easy accessibility of system components through front door
Temperature control	heating up to 80 °C
Application parameter	
Consumables	completely contained in the required kit sealed, pre-filled reagent strips or plates
Lysis step	automated in the device (dependent on the source material)
Extraction routines	pre-installed protocols (optimized for the most varied source materials)
Piercing function	removing the sealing film from the reagent strips and plates not necessary
Cross contamination	completely precluded through sealed reagent strips and plates
Tips	max 32 per preparation with 1000 µl each
Samples	
Sample capacity	up to 16 preparations in parallel processing of different source materials possible with identical pipetting protocols
Sample preparation	pre-insertion of the pipette tips, samples and elution tubes into the sample tray insertion of pre-filled reagent strips/plates into the sample tray
Sample volume	up to 2 ml or up to 50 mg
Elution	separate storage vessels with cover
Elution volume	100 - 500 µl (adjustable)
Accessories and kits	
sample tray	carrier for the pre-insertion of all consumables and samples
priming station	rack for easy preparation of the sample tray
kits	DNA extraction and RNA extraction from different source materials
Other technical data	
Weight	Approx. 28 kg
Dimensions (W x H x D)	380 mm x 435 mm x 530 mm

Electrical variables	
Power supply	110 – 230 V AC, 50/60 Hz
Protection	2 x T 4A H 250V
max power consumption	160 VA
PC interface	USB
Interference suppression (electromagnetic compatibility)	Interference suppression in compliance with the rules BMPT Vfg. 243/1991 and EN 55022 class A
Environmental conditions	
Temperature during operation	5 – 35 °C
Humidity during operation	max. 80 % at +30 °C
Temperature during storage	-10 – 55 °C
Humidity during storage	max. 80 % (use desiccant)

3 Safety instructions

3.1 General notes

For your own safety and to ensure error-free and safe operation of the InnuPure C16, please read this chapter carefully before using the appliance.

Comply with all safety instructions in this user manual and pay careful attention to all messages and notes which are displayed on the screen by the program.

You must also comply with the safety instructions on the labels as well as the information on handling, storage and disposal of the kits.

Besides the safety instructions in this user manual and the local safety regulations that apply to the operation of the device the general applicable regulations regarding accident prevention, occupational health and safety and environmental protection have to be observed and complied with.

References to potential dangers do not replace the work protection regulations which must be observed.

3.2 Symbols and signal words used in the user manual

The user manual uses the following symbols and signal words to indicate hazards or instructions. The safety instructions are always placed before an action.



CAUTION

Indicates a potentially hazardous situation.

If it is not prevented light or minor injuries and material damage can result.



ATTENTION

Indicates a potentially hazardous situation.

Unless avoided, the product or items in its vicinity may be damaged.



IMPORTANT

Indicates application hints and other especially useful information without any resulting hazardous or damaging situations.



ENVIRONMENTAL PROTECTION

Indicates application hints and information to aid the proper disposal and handling of the substances and materials used.

3.3 Safety marking at the InnuPure C16

Safety and notice symbols have been attached to the InnuPure C16 whose content must always be observed.

Damaged or missing safety and notice symbols can cause incorrect actions leading to personal injury or material damage! The symbol labels must not be removed! Damaged symbol labels must be replaced without delay!



Figure 1 Safety symbols at the front and rear of the InnuPure C16

Warning symbol	Meaning	Remark
	Warning against a hazard location	Warning against mechanical danger from moving equipment parts
	Biological hazard	Warning against damage from biological substances. Observe corresponding protection instructions!
	Reaching prohibited during operation	Warning against crushing by moving parts.
Notice symbol	Meaning	Remark
	Before opening the device always disconnect the mains plug	Before opening the device: Switch off the device and disconnect the mains plug from the mains socket and the device.
	Observe the instructions for use.	Prior to starting work read the instructions for use.
	WEEE identification of electrical and electronic equipment	The device must be disposed of separately from household waste as electrical and electronic waste after its useful life has expired.
2x4 AT, 250V	Identification of the internal fuse	Only use the specified fuses!

3.4 Technical condition

The InnuPure C16 corresponds in its design and construction to the current state of the art technology. Unauthorized modifications or changes, especially such that affect the safety of the staff and the environment, are generally not allowed.

Observe the following notes:

- ☐ The operator must only operate the device in a sound and operationally safe condition. The technical condition must always comply with the legal requirements and regulations.
- ☐ Prior to every use the device must be checked for damage and sound condition.
- ☐ Any changes in the device affecting its safety must be reported by the operating personnel to the operator without delay.

3.5 Requirements for the operating personnel

Observe the following notes:

- ☐ The InnuPure C16 must only be commissioned, operated and serviced by trained personnel instructed in technical safety.
- ☐ The operation or servicing of the device by minors or individuals under the influence of alcohol, drugs or medication is not permitted.
- ☐ It must be ensured that only authorized personnel works at the device.
- ☐ The operating personnel must be familiar with the dangers arising from the substances used. The appropriate protective equipment must be used.

3.6 Safety instructions, transport and installation

Observe the following notes:

- ☐ Only transport the device in its original packaging! Ensure that all transport protections have been fitted and the device is completely empty, cleaned and decontaminated.
- ☐ The InnuPure C16 may only be installed by service personnel from Analytik Jena AG or by persons authorized by Analytik Jena AG.
- ☐ To prevent health damage the following must be observed when moving the device in the laboratory (lifting and carrying):
 - For reasons of safety 2 persons are required to transport the device and must position themselves on both sides of the equipment.
 - Since the device does not have handles, grip the device firmly with both hands at the lower end, lifting it simultaneously. Make sure the door is closed. Do not hold from the door area.
 - The guide values and statutory limits for lifting and carrying loads without auxiliary equipment must be observed and adhered to.

3.7 Safety instructions - operation

Observe the following notes:

- ☐ The operator of the InnuPure C16 must make sure before each commissioning that the condition of the device including the safety equipment is sound. This applies in particular after each modification or extension of the device or its repair.
- ☐ The device must only be operated if all protective equipment (e. g. doors) are present, properly installed and fully operational.
- ☐ Free access to the device switch on the back of the enclosure must be ensured during operation.
- ☐ During operation and immediately after aborting an extraction protocol the operator must not reach with his hands into the device chamber. Otherwise the operator may get burned at the magnet heating adapters (max. 80 °C). After aborting an extraction protocol it is necessary to wait 5 min. before performing additional tasks inside the device.
- ☐ The ventilation equipment on the device must be in good working condition. Covered vents or ventilation slits etc. may cause the device to break down or may cause damage to it.
- ☐ The mains plug must only be plugged into a power outlet with protective ground connection. The device may only be connected to power sources whose nominal voltage is the same as that on the nameplate of the equipment. The protective effect must not be invalidated by the use of an extension line which does not have a protective conductor.
- ☐ Do not introduce any objects into the device and prevent fluids from entering the device through openings or gaps.
- ☐ Do not short circuit the device and only use fuses in accordance with the specifications in the technical data.

3.8 Handling hazardous substances

Even with intended use there is a risk of health damage when handling hazardous substances. The operator is solely responsible for the compliance with all safety requirements to protect individuals and property when handling radioactive, infectious, toxic, caustic, flammable and other hazardous substances.

- ☐ Control the handling of hazardous substances in accordance with the safety category of the lab, the details in the manufacturer safety data sheets and additional national and international regulations (WHO, "Laboratory Biosafety Manual").
- ☐ Wear personal protective equipment when working at the device.
- ☐ Observe all notices on the cleaning and decontamination of the device.

3.9 Chemical resistance of the device

Aggressive substances may damage the device. Although the materials used are resistant to most commonly use substances, material damage from aggressive substances may not be precluded.

- ☐ Before using aggressive substances (e.g. acids, bases or organic solutions) check whether the materials in direct contact with the substances are resistant to them.
- ☐ Only use substances compatible with the materials listed.
- ☐ If in doubt contact Analytik Jena AG.

Components	Material
Filter tips	PP
Piston seal	Aluminum, stainless steel, PTFE, rubber (NBR 70) The pistons are not contaminated with sample if the filter tips are used.
Reagent cups	PP or PTFE

Overview 1 Components and materials in direct contact with the sample

The above-mentioned components are not resistant to the following substances:

- ☐ hydrogen fluoride (HF/hydrofluoric acid)
- ☐ highly concentrated acids
- ☐ cleaning powder
- ☐ paint thinner
- ☐ naphtha
- ☐ gasoline
- ☐ acetone
- ☐ cleaning spray
- ☐ ozone

3.10 Behavior during emergencies

- ☐ If there is no immediate danger of injury switch the device switch of the InnuPure C16 into the "0" position during dangerous situations or accidents when possible and/or disconnect the mains plugs from the mains outlets!

Because a rapid response can save lives during an emergency, the following has to be ensured:

- ☐ The operating staff must be familiar with the location of safety equipment, accident and danger alarms as well as first aid and rescue equipment as well as their handling.
- ☐ The operator is responsible for the respective training of the operating staff.
- ☐ All equipment for first aid (first-aid kit, eyewash bottles, stretcher, etc.) as well as equipment for firefighting (fire extinguishers) must be within reach and easy to access. All equipment has to be in a sound condition and should be checked regularly.

3.11 Standards and directives

The device was manufactured according to the currently valid technology regulations and the approved safety related regulations.

When constructing the device the relevant safety and health requirements of the applicable laws, standards and regulations were applied. The safety of the device is confirmed by the CE mark and the declaration of conformity.

Information regarding safety corresponds to the currently valid regulations of the European Union. In other countries the applicable laws and country specific regulations have to be complied with.

Besides the safety instructions in this user manual and the local safety regulations that apply to the operation of the device the general applicable regulations regarding accident prevention, occupational health and safety and environmental protection have to be observed and complied with.

References to potential dangers do not replace the work protection regulations which must be observed.

4 Technical description

4.1 Basic system design

The InnuPure C16 is a flexible and efficient extraction system for the fully automated isolation and purification of nucleic acid. The system, developed and produced in Germany, has been designed for low sample throughput. A large selection of different source materials can be used. The system combines a unique technology for handling fluids with an extremely fast walk-away principle.

The InnuPure C16 is equipped with pre-installed extraction protocols to prevent time-consuming programming. The high degree of flexibility of the InnuPure C16 enables the parallel isolation of DNA and RNA from up to 16 samples. The work-intensive process of sample lysis which so far mostly had to be performed separately, now is part of the automatic extraction process (dependent on the source material).

The nucleic acids to be isolated adsorb at surface-functionalized magnetic particles. The necessary extraction chemicals are added manually as necessary and enable the purification of ultrapure nucleic acids with excellent yields.

The extraction principle prevents cross contamination effectively, a problem often occurring in vacuum-based extraction methods. The isolated nucleic acids can then be used immediately for further downstream applications

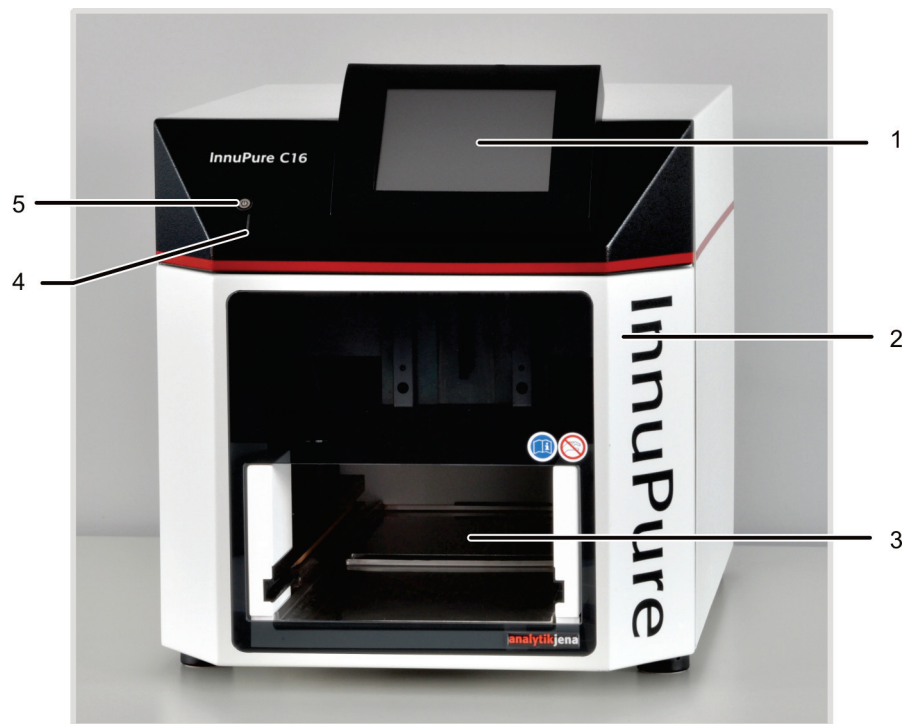
Different specifically optimized extraction kits are available for the InnuPure C16:

- ☐ for the isolation of genomic DNA
- ☐ for cellular RNA
- ☐ for viral or bacterial nucleic acids
- ☐ for the processing of forensic samples

Dependent on the application the extractions take between 45 and 75 minutes.

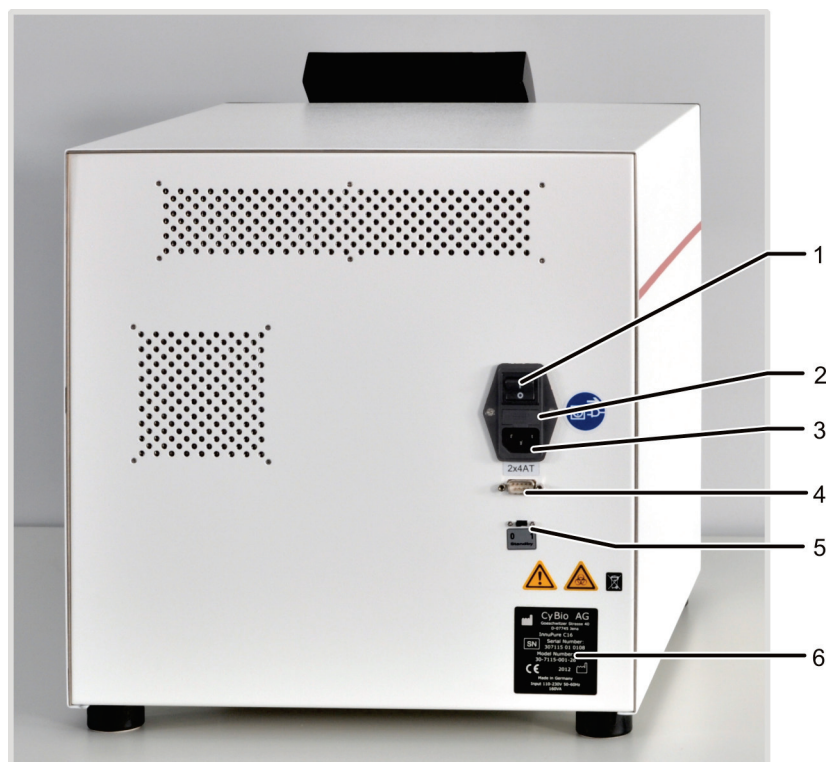
4.2 Design, connections, indications

The InnuPure C16 is a stand-alone device. The operation and device control take place via the control unit HID-Pro 320 attached to the front. The sample processing follows pre-installed protocols tailored to the extraction kits. The kits include all reagents necessary for extraction permitting the extraction to run fully automated. During operation the front door of the InnuPure C16 is closed. For the status control of the device the touch sensor has been equipped with an LED strip. This illuminates dependent on the operating state green or red or indicates the use of the touch sensor by alternating green/red flashing.



- | | | | |
|---|--------------------------|---|-----------------------|
| 1 | Control unit HID-Pro 320 | 4 | LED status indication |
| 2 | front door | 5 | Touch sensor |
| 3 | sample tray adapter | | |

Figure 2 Front view of the Innupure C16



- | | | | |
|---|------------------|---|--|
| 1 | Mains switch | 4 | RS 232 interface |
| 2 | Fuse holder | 5 | bridging switch of the touch sensor (standby switch) |
| 3 | Mains connection | 6 | Type plate |

Figure 3 Rear connections and switches at the Innupure C16

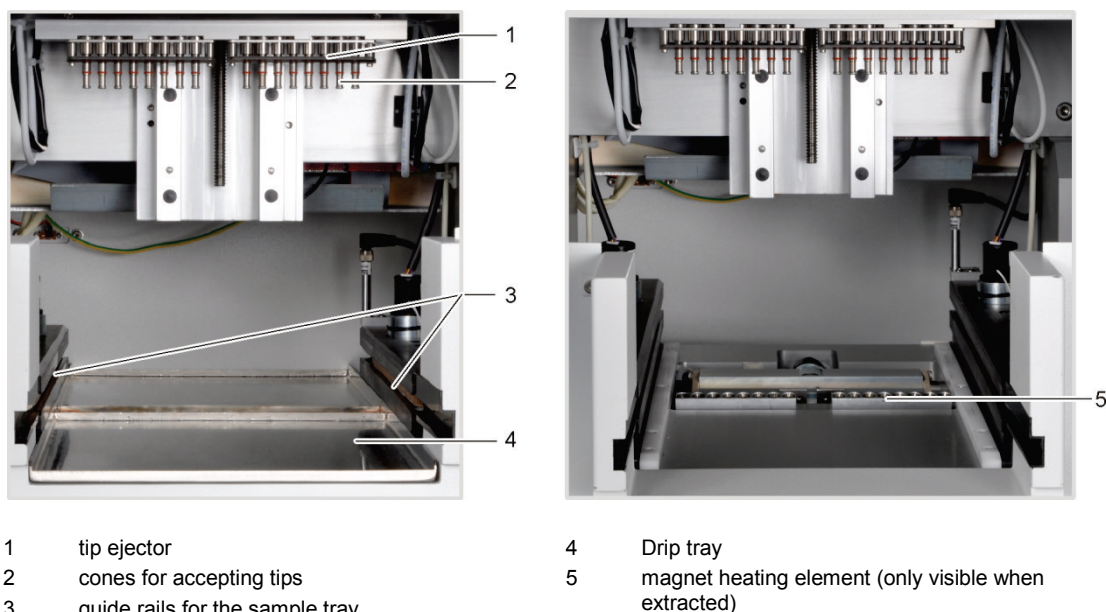


Figure 4 Device view with open front door

All pre-manufactured reagent packs necessary for the extraction process (including all buffer solutions), the filter tips and the elution vessels are placed onto the sample tray. Dependent on the number of samples reagent plates (deep well plates) with eight sample positions or reagent strips for individual samples will be used. Thus within a single extraction protocol one sample in a reagent strip up to a maximum of 16 samples in two deep well plates can be processed. Optionally available adapters are used to accept the reagent strips. Reagent plates are placed directly into the sample tray. For populating the sample tray the tray must be placed into the priming station supplied.

Positions 1 and 3 of the strips and plates are used as ejection location for used tips later in the process. For the correct operation of the tip ejection it is absolutely necessary that these positions are fully opened (at least 7 mm diameter) with the optional perforation tool or another suitable tool before starting.

The loaded sample tray is inserted into the adapter in the front door (3 in Figure 2, p. 16) and then automatically pulled into the correct position in the InnuPure C16.

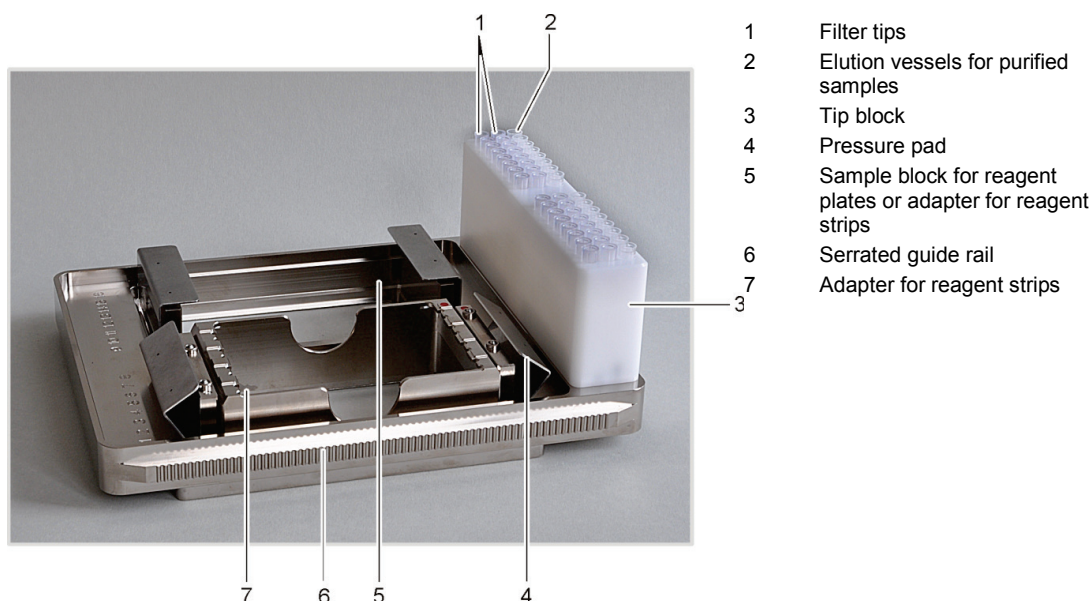


Figure 5 Sample tray

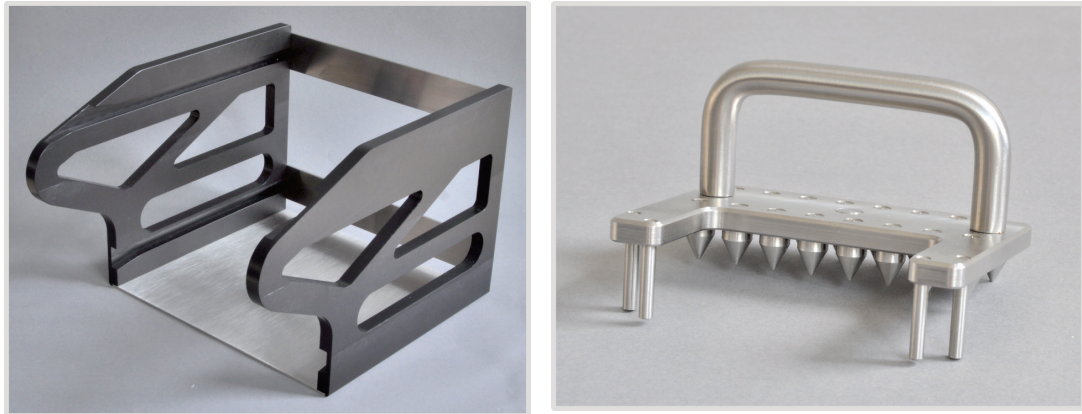
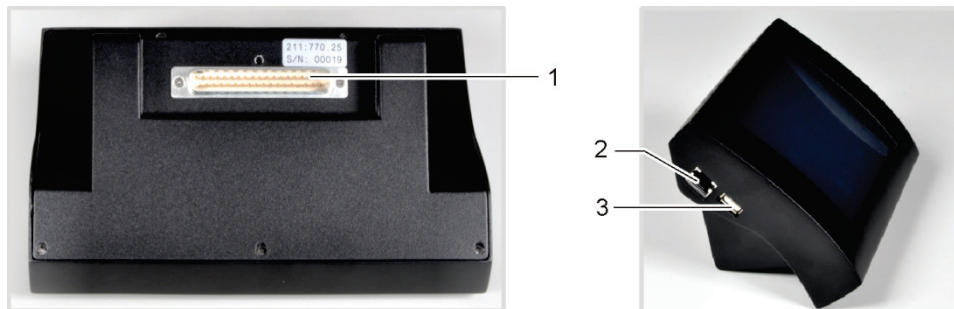


Figure 6 Priming station and optionally available perforation tool

The InnuPure C16 uses the flexible and portable control unit HID-Pro 320 with the large 5.7" touchscreen. The integrated PC on Windows CE basis enables the use of typical Windows functions with a clearly structured menu interface. Thus, the entire system becomes a stand-alone device. For the review of the running extraction the status of the current step is displayed in realtime. The user can thus follow every routine clearly and continually. Via the USB port the isolation protocols can be transferred and a simple software update is also possible.












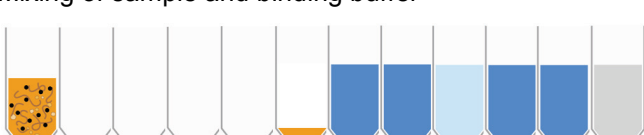
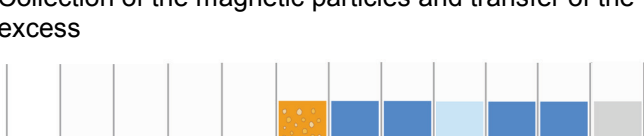


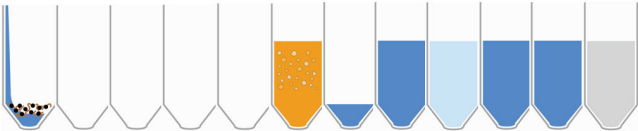
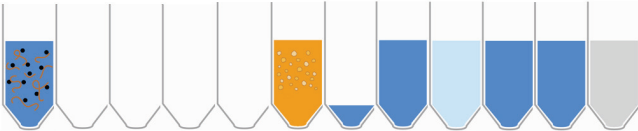
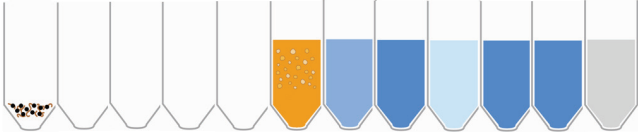
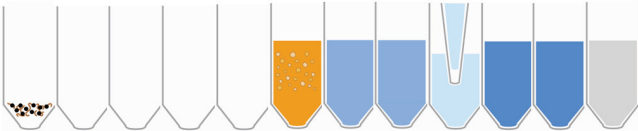
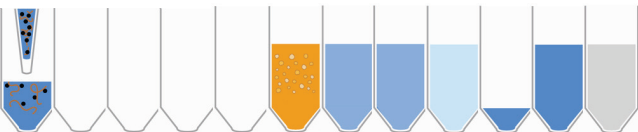
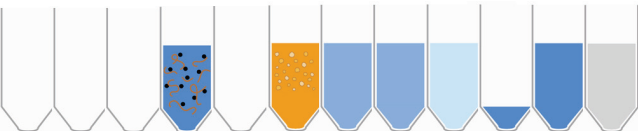
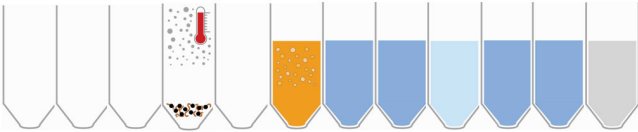
1 interface to connect to the InnuPure
2 network connection

3 USB port

Figure 7 HID-Pro 320

4.3 Principle of operation

<p>Pre-filled reagent structure</p>  <p>  Magnetic Beads  Washing Solution  Lysis Solution  Water  Binding Solution  Elution Buffer </p>	<p>Reagent structure</p> <p>The reagent strips or reagent plates are completely pre-filled and contain in addition to the magnetic particles all reagents necessary for the extraction process for the binding, washing and elution of nucleic acids.</p> <p>After starting an extraction protocol the InnuPure C16 takes the tips provided from the corresponding row in the tip block of the sample tray.</p>
<p>External lysis</p>  <p>Internal lysis</p> 	<p>Lysis</p> <p>Dependent on the type of source material the lysis is processed either inside the device (internal) or must be performed manually outside the device (external).</p> <p>The lysis step for the corresponding source material has been described in detail in the manual for the respective extraction kit.</p>
<p>Mixing of lysate + magnetic particles</p>  <p>Transfer of binding buffer to the sample</p>  <p>Mixing of sample and binding buffer</p>  <p>Collection of the magnetic particles and transfer of the excess</p> 	<p>Binding</p> <p>With the aid of the binding buffer the nucleic acids are bound to the magnetic particles</p> <p>Dependent on the protocol sequence with external or internal lysis the binding of the nucleic acids takes place in different positions of the reagent structure</p> <p>In the external lysis the mix of lysed sample and MAG suspension is first homogenized by pipetting on and off. The binding buffer is then transferred to the sample.</p> <p>During the next step the magnetic unit is moved to the floor of the work cavity. The magnetic particles with the bound nucleic acids are held by the magnetic field on the floor of the work cavity.</p> <p>The excess of binding buffer is transferred to the original holding position by pipetting off.</p>

<p>Washing buffer transfer</p>  <p>Washing</p>  <p>Collection of the magnetic particles and transfer of the excess</p> 	<p>Washing of the nucleic acids</p> <p>The magnetic particles remain in the work cavity and the washing buffer is then transferred there. By pipetting different washing buffers on and off the nucleic acids are washed.</p> <p>The number of washing steps and volume and type of washing buffer depend on the type of the source material used. In addition, the buffers differ in the case of DNA or RNA extraction.</p> <p>Between each washing step the magnetic particles are collected with the bound nucleic acids from the cavity floor. The corresponding wash excesses are pipetted off and returned to their original holding position.</p>
	<p>Tip washing</p> <p>To prevent the carry-over of washing solution residue, the tips used are flushed between specific washing steps.</p>
<p>Removal of the washing solution from the 1st work cavity</p>  <p>Discharge of the washing solution into the 4th work cavity</p> 	<p>Change of the work cavity</p> <p>Prior to the final washing step the washing solution is removed completely from the 1st work cavity and transferred by pipetting over into the 4th work cavity.</p> <p>The quality of the already washed nucleic acids is significantly improved by the transfer into a clean work cavity. Any lysis residue at the walls are retained in the "dirty" cavity and only the already washed nucleic acids bound to the magnetic particles are transferred on.</p>
	<p>Ethanol removal</p> <p>The removal of ethanol residue at the magnetic particles and within the samples takes place via a drying step. In this step a heating is activated in the cavity floor causing the ethanol residue to evaporate.</p>

<p>Transfer of the elution buffer into the work cavity</p> <p>Heating of the elution buffer</p> <p>Elution and collection of the magnetic particles</p> <p>Change of the work cavity</p>	<p>Elution</p> <p>The elution volume can be adjusted in the range from 100 to 500 µl and is defined at the start of the protocol.</p> <p>The correspondingly selected volume is removed from the holding position and transferred to the magnetic particles in the work cavity.</p> <p>The elution process represents the separating of the nucleic acids from the magnetic particles. This is improved by heating the elution buffer and mixing well through pipetting on and off.</p> <p>To be able to transfer the eluates free from magnetic particles into the elution vessels the eluate is transferred once again into a new work cavity. There the remaining magnetic particles are finally collected at the cavity floor.</p>
	<p>Eluate transfer</p> <p>The nucleic acids are now extracted, are transferred into the elution tube and are available for further downstream applications.</p>

Note:

Filling levels and filling colors are only shown for illustration and do not match the actual filling levels and colors of the kit reagents.

5 First commissioning

5.1 Site requirements

5.1.1 Installation conditions

The following requirements are placed on the climatic conditions in the operating room of the InnuPure C16:

- ☐ Temperature range: +5 °C to +35 °C
- ☐ Max. humidity: 80 % at 30 °C

The following requirements are placed on the location of the InnuPure C16:

- ☐ Do not locate the device directly near a door or window.
- ☐ Place the device on a stable surface.
- ☐ Do not locate the device near sources of electromagnetic interference.
- ☐ Avoid direct sunlight and radiation from heaters onto the device, if necessary ensure air conditioning.
- ☐ Never cover the front door and the air vents of the device with other equipment or installations!
- ☐ Keep a safety distance of at least 5 cm from the rear of the device to other equipment or walls!

5.1.2 Space requirement

The space requirement results from the device dimensions:

Closed device (W x D x H):	380 mm x 530 mm x 435 mm
Device with open front door (W x D x H):	380 mm x 920 mm x 435 mm
Sample tray (W x D x H):	200 mm x 250 mm x 83 mm
Priming station (W x D x H):	210 mm x 260 mm x 165 mm

The loaded sample tray is moved through the opening in the door into the device. The device door must be opened for cleaning and maintenance purposes and must therefore be added to the dimensions.

The air vents on the rear of the device must remain unobstructed to ensure air circulation.

5.1.3 Energy supply



WARNING!

The InnuPure C16 must only be connected to a properly grounded mains outlet in accordance with the voltage specifications on the type plate!

The InnuPure C16 is operated on single-phase alternating current. The installation of the electrical equipment of the laboratory must comply with the standard DIN VDE 0100. After the connection point an electrical current in accordance with the standard IEC 38 must be available.

5.2 Connecting the InnuPure C16 and switching it on/off



IMPORTANT

Retain the transport packaging! Return transport for service must be in the original packaging. This alone prevents transport damage.

Connecting the InnuPure C16

1. Take the InnuPure C16 out of the packaging.
 2. Check the device for completeness and soundness.
 3. Insert the control unit HID-Pro 320 into the interface on the front of the InnuPure C16 (1 in Figure 2 p. 16)
 4. Connect the mains cable at the rear.
- ✓ **The InnuPure C16 is now ready for operation.**

Switching on the InnuPure C16



ATTENTION!

When switching on the InnuPure C16 no USB stick must be connected to the control unit HID-Pro 320. The user data on the HID-Pro 320 could be overwritten.

1. Switch the InnuPure C16 on from the mains switch at the equipment backplate.
2. Activate the InnuPure C16 via the touch sensor on the front of the device. Touch the sensor for approx. 3 s until the red illuminated status indication changes to green and the control unit HID-Pro 320 switches on.

Note:

The switch is a capacitive button that could be damaged by strong pressure. Only touch the button lightly.

- ✓ **The InnuPure C16 is initialized automatically. The process takes approx. 30 s. The end of initialization is signaled by a beeping sound. Only then may entries be made via the control unit HID-Pro 320.**

3. Enter the following password:
 User name: Administrator
 Password: IPC16

✓ **The InnuPure C16 is now ready for operation.**

Note:

User administration is enabled using the menu item MENU | LOGIN AT START. Disable the command if you do not want to use user administration. This requires administrator rights. At the next device start the last logged in user is automatically logged in.



Figure 8 Start window

Switching off the InnuPure C16

Wait until all processes of the current extraction protocol have completed. Then switch the InnuPure C16 off from the mains switch at the equipment backplate.

Alternatively, you can put the InnuPure C16 into sleep mode. To this end touch the touch sensor for approx. 3 s until it illuminates red and the indication at the control unit HID-Pro 320 goes out.

Note:

During sleep mode the InnuPure C16 is not switched off completely but consumes power. To switch off the InnuPure C16 completely, switch off the device from the mains switch at the equipment backplate.

Switching off the touch sensor

The touch sensor can be bypassed. Then the device can no longer be switched on and off from this switch.

If you do not want to use the touch sensor, move the switch (5 in Figure 3 p. 16) to position "I".

✓ **The LED of the touch sensor illuminates permanently green. Now the InnuPure C16 only can be switched on and off at the mains switch.**

6 Operation

6.1 Preparation of the buffers and solutions

All buffers and solutions are provided in pre-filled and sealed reaction cups (reagent plates or strips) dependent on the isolation routine and source material. The preparation of the sample tray has been described in detail in each kit manual and section "Preparing the sample trays" p. 25.

Follow the instructions described in the preparatory steps within the kit components of the kit manual. It is recommended to preheat the thermal mixer for some steps of the lysis in accordance with the kit manual.

6.2 Preparing the sample trays and inserting them into the InnuPure C16



CAUTION! Nickel allergy!

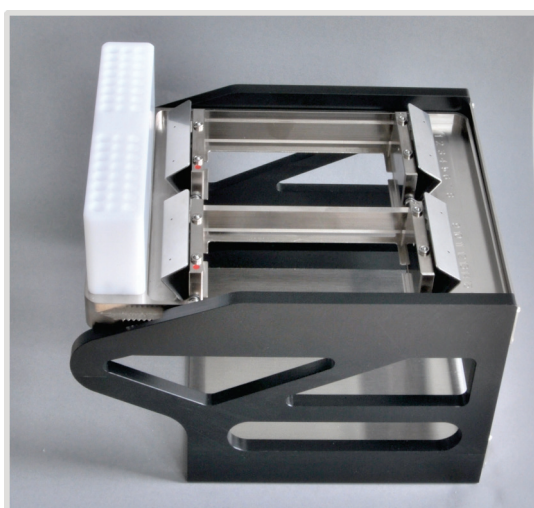
The sample tray is coated with nickel.



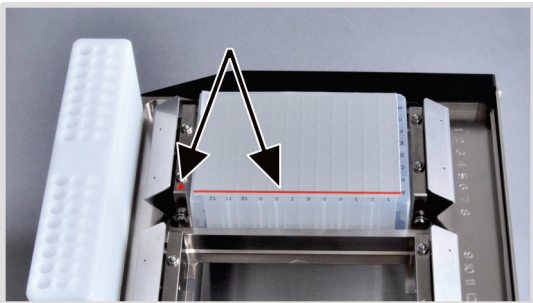
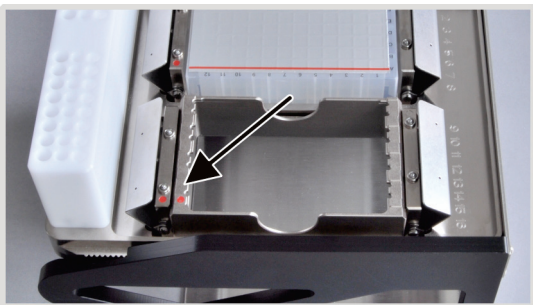
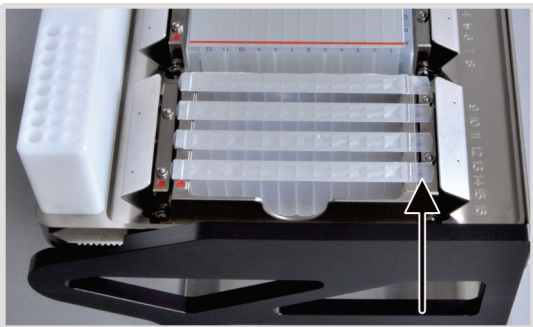
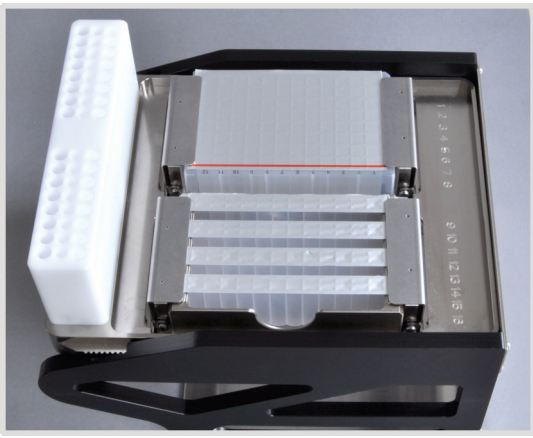
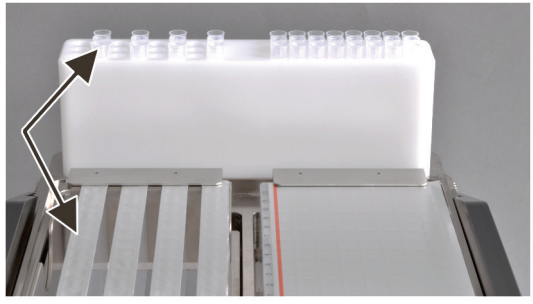
IMPORTANT!


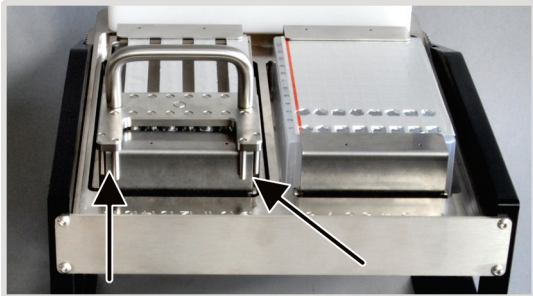
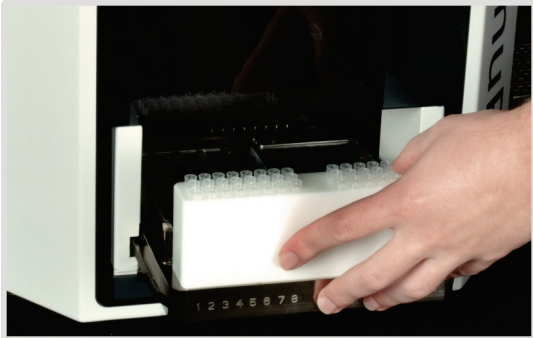

Use the priming station to populate the sample tray. The filter tips are longer than the tip block and would impact against the table top!!

Prior to extraction the sample tray must be loaded with the reagent plates and/or reagent strips of the kit used. In the example the sample tray is populated with a reagent plate and four reagent strips. When inserting the plates and strips always ensure the correct orientation!



1. Move the sample tray into the priming station and fold the holding-down clamp at the sample tray upwards.

	<p>2. Place the reagent plate into the holder of the sample tray. The red line on the cover film must point to the red dot at the holder.</p>
	<p>3. Place the adapter for the reagent strips into the holder. Here, too, the red marking on the adapter must point to the red point at the holder.</p> <p>Caution: Load the sample tray evenly in both adapters (see below)!</p>
	<p>4. Place the strips into the adapter. The long tab marked with the label "AJ" must point to the engraved numbers on the sample tray.</p>
	<p>5. Fold down the holding-down clamp to prevent the plates and strips to be pulled out of the holder during the extraction process.</p>
	<p>6. Place the filter tips into the two rows with the smaller drill holes. Place the elution vessels into the wider drill hole at the edge of the tip block. Empty sample positions do not need to be filled. Especially with the strips make sure that for every strip the tips and the elution vessel are in the corresponding positions in the tip block (arrows in figure on the left)!</p>

	<p>Caution</p> <p>The number of filter tips per sample and their positioning (1st or 2nd row in the tip block) depends on the reagent kit used. Pay attention to the kit description!</p>
<p>7. Open all cavities of positions 1 and 3 on the strips and plates by piercing the film with an unused filter tip and widening it or using the optionally available perforation tool (see item 8). For the strips, position 1 is at the tab labeled "AJ". On the plates the position numbers are attached on the side.</p> <p> Caution: Open the cavities fully (at least 7 mm in diameter)! The used filter tips are ejected into these cavities during the extraction protocol. If the cavities are closed or insufficiently opened, the tips may be thrown out of the cavities after ejection due to travel. This may result in errors during the extraction process and in adverse cases even a cancellation of the protocol.</p>	
	<p>8. When using the perforation tool, place it onto the edges of the rear holding-down clamp with the four long bolts sitting against the edges. Then press the tool down until the stop to make the tips pierce through the sealing film and creating large openings. The use of the tool is identical for reagent plates and strips.</p>
<p>9. Continue preparing the reagent strips and plates in accordance with the kit descriptions.</p> <p>10. Switch on the InnuPure C16 and wait for the device initialization to complete, which is signaled by a beeping sound.</p>	
	<p>11. Move the loaded sample tray with the reagent strips forward into the adapter on the front of the InnuPure. The serrated rails at the side of the sample tray must protrude into the grooves of the adapter. After pressing lightly against the tip block the sample tray is automatically pulled into the device.</p> <p> CAUTION! Risk of crushing! Immediately let go of the sample tray once it is being pulled in. Otherwise there is a risk of your hand being crushed.</p>
<p>12. Start the extraction protocol:</p> <ul style="list-style-type: none"> – In the start window press the button [SELECT PROTOCOL]. – Select the desired extraction protocol and press [START] (see chapter "Starting an extraction protocol" p. 30). <p>13. After completion of the protocol press again lightly against the tip block. The sample tray is then automatically moved out of the sample block.</p>	

14. Remove the sample tray from the adapter of the InnuPure and move it back into the priming station.



15. Close the elution vessels.



IMPORTANT! Load the sample tray evenly

For an extraction protocol both adapters in the sample tray must be filled in order to be balanced and to allow for optimum movement of the tray inside the device to the necessary positions.

- ☐ If more than one reagent strip are processed during the extraction protocol, insert two adapters into the tray and distribute the strips evenly between them.
- ☐ If only one sample is extracted, then place an adapter with an empty strip onto the second adapter in the sample tray.
- ☐ If you process the samples in a reagent plate, populate the second adapter with an empty plate.

6.3 Operating InnuPure with HID-Pro 320

Device control is via the HID-Pro 320 unit. After switching on the InnuPure C16 a device initialization lasting approx. 30 s is automatically performed, testing various device functions and moving the electro-mechanical drives into their start positions. The completion of initialization is signaled by a beeping sound. Only then may entries be made in the HID-Pro 320 unit!

6.3.1 Overview of the InnuPure C16 program

All program functions are easily accessible via the start window:

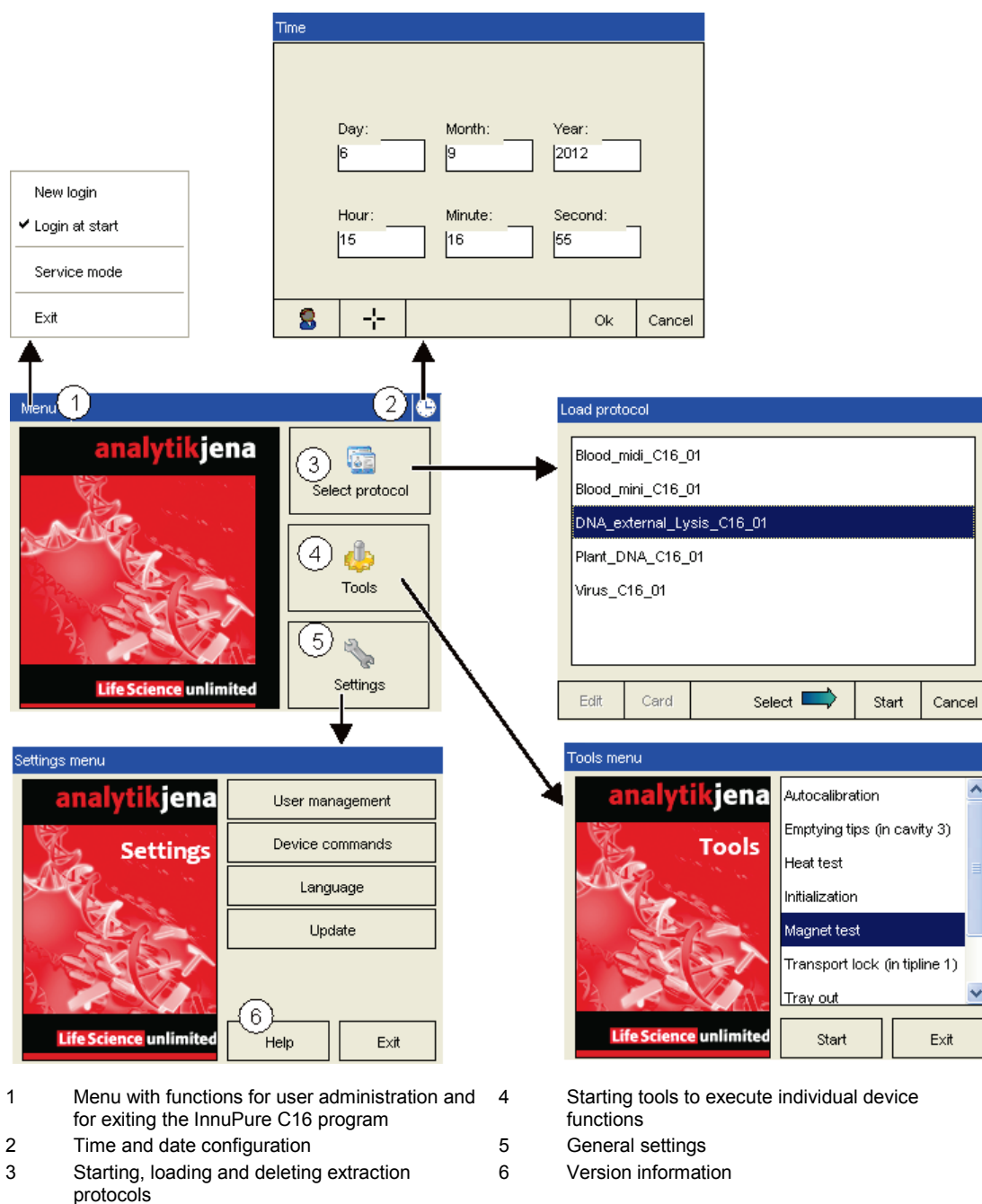


Figure 9 Program overview of the InnuPure C16

Using the [MENU] (1) button in the top left corner you open a menu with the functions for disabling the user login when switching on the InnuPure C16 and for changing user logins (see chapter "Work with user ID management" p. 36). A user logged in with administrator rights can leave the program with [EXIT] and arrives at the operating system of the HID-Pro 320 (password "ipex"). The [SERVICE MODE] is only accessible to service staff.

Hidden behind the clock symbol (2) in top right corner there is a window for configuring the date and time of the InnuPure C16 program (see chapter "Configuring the time" p. 39).


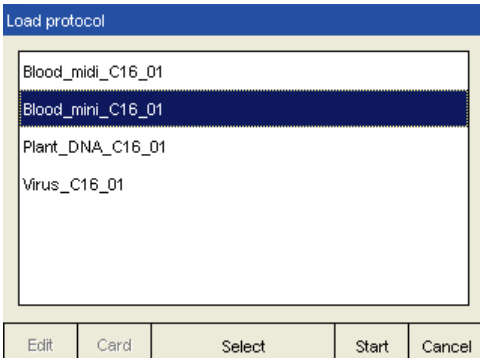
Using the [SELECT PROTOCOL] button (3) you select an installed extraction program and start it (see chapter "Starting an extraction protocol" p. 30). A user with administrator rights can also install additional extraction protocols in this window and delete unnecessary protocols (see chapter "Copying, moving or deleting extraction protocols" p. 33). Via [TOOLS] (4) you start programs for testing or executing individual device functions, e.g. the control of the heating function or the ejection of the filter tips.

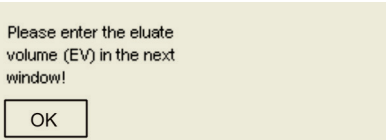

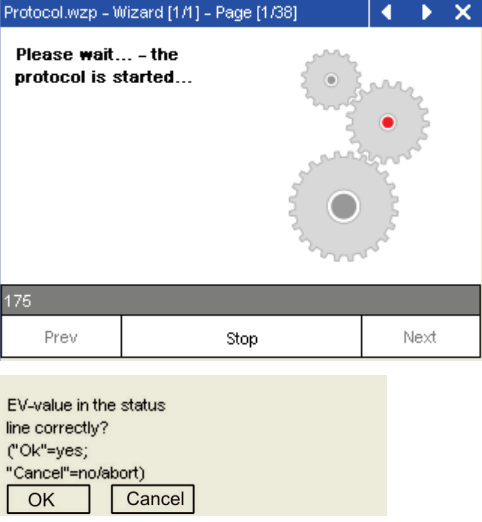
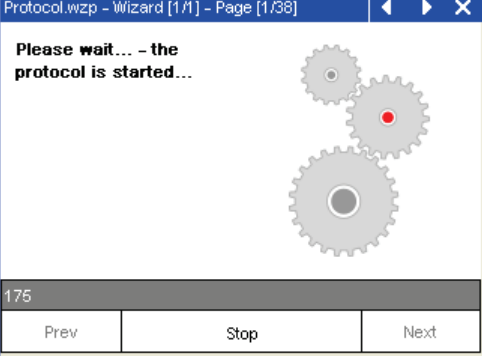
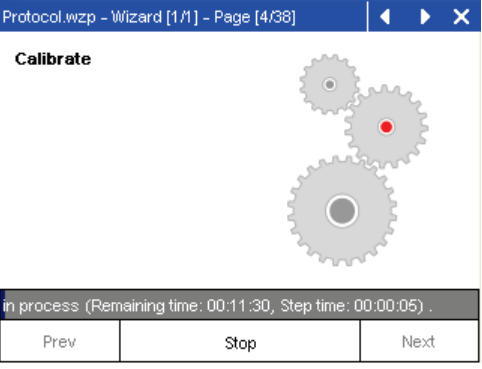
With [SETTINGS] (5) you gain access to the following program functions:

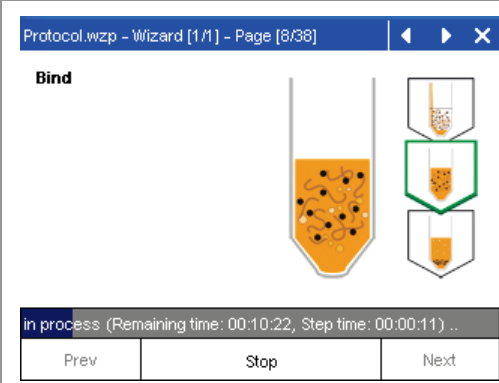
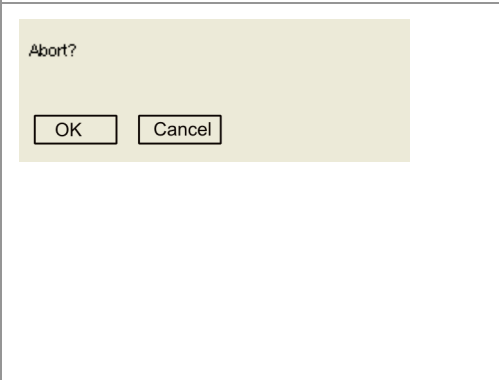
- ☐ User administration – "Creating/modifying a user profile" p. 36
- ☐ Device functions – "Switching the interior light on and enabling the touch sensor" p. 38
- ☐ Language selection – (currently only English)
- ☐ Software update "Software update" p. 44.

Information about the installed software version is available in the SETTINGS MENU via the [HELP] button (6).

6.3.2 Starting an extraction protocol

	<p>1. Press the [SELECT PROTOCOL] BUTTON.</p>
	<p>2. Select the desired protocol from the list.</p> <p>3. Press the [START] button.</p>

 	<p>4. Enter the eluate volume in 25 µl steps. If the volume has not been entered in 25 µl steps, the volume is rounded off by the program. Volume values: 100, 125, 150,...500 µl</p>
	<p>5. Check that the entered eluate volume has been accepted in the status line of the window in accordance with the inputs and confirm the query with [OK].</p>
	<p>A check is performed during protocol start whether the sample tray is already in the device. If not, a prompt appears to insert the sample tray now.</p>
	<p>This is followed by a device calibration. The status line displays a blue progress bar, the remaining time till the end of the extraction protocol and the remaining time of the current step.</p>

	<p>Whilst the extraction protocol is run the current step is displayed and symbolized by a pictograph. On the right side of the window the pictographs of the previous, current and next step are also displayed from top to bottom.</p>
	<p>By pressing the [STOP] button the extraction protocol can be aborted after acknowledging the message "ABORT?" with [OK]. However, the current command will still be completed. Select [CANCEL] if you want to continue the extraction protocol. To return to the start window after aborting a protocol, press the [x] button at the top right in the window.</p> <p>Note During a step in which the filter tips are ejected the [STOP] button is disabled.</p>

**CAUTION! Risk of burns!**

Do not reach into the device interior immediately after aborting the extraction protocol. The magnet elements may be up to 80 °C hot at this time but cool down to 50°C within 5 min.

6.3.3 Copying, moving or deleting extraction protocols



IMPORTANT

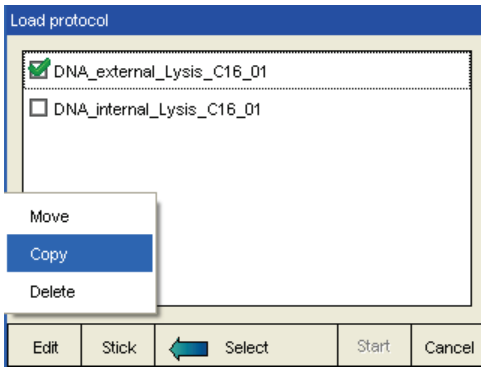
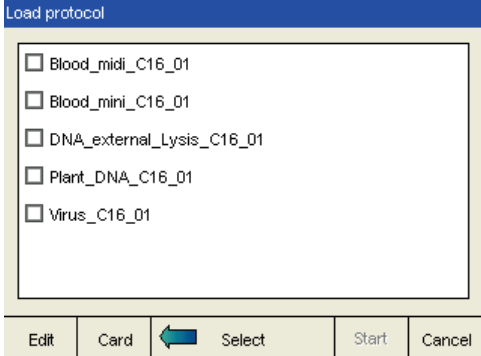
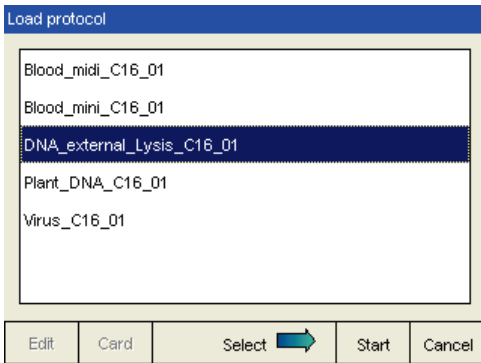
Administrator rights are required for moving, deleting or copying extraction protocols!

Extraction protocols have already been pre-installed on the InnuPure C16. It might, however, be necessary to install protocols for a new reagent kit and to delete unnecessary protocols or move them temporarily to external data carriers. This administration of the extraction protocols takes place in the protocol window.

The data transfer when moving or copying always takes place between a USB stick (Stick) and the memory card in the HID-Pro 320 (Card). A folder "Wizard" must be present on the USB stick containing the program folders to be copied or to which program folders from the memory card of the HID-Pro 320 are moved.



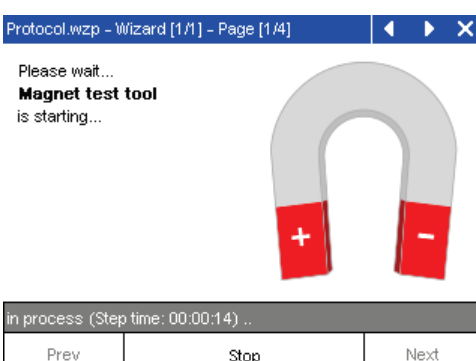
In the example, copying of the protocol "DNA_external_Lysis_C16_01" to the memory card of the HID-Pro 320 is explained step by step.

	<ol style="list-style-type: none"> 1. Switch on the InnuPure C16 and wait for the device to initialize. 2. Connect the USB stick with the file to be copied in the folder "Wizard" to the HID-Pro 320. 3. Press the [SELECT PROTOCOL] BUTTON.
	<ol style="list-style-type: none"> 4. Press [SELECT], this makes the menus [EDIT] and [CARD] available. Now, the [START] cannot be actuated. <p>The [EDIT] contains the three functions:</p> <ul style="list-style-type: none"> <input type="checkbox"/> MOVE – moving a file to a different data carrier. <input type="checkbox"/> COPY – copying a file to a different data carrier. <input type="checkbox"/> DELETE – deleting a file on the current data carrier. <p>Using the buttons [CARD] or [STICK] you can move between the data carriers.</p>
	<ol style="list-style-type: none"> 5. Press [CARD] and in the menu select the data carrier containing the protocol to be edited, here STICK.

	<ol style="list-style-type: none">6. Highlight the desired protocols in the list displayed.7. In the [EDIT] menu select the menu item, here COPY, and acknowledge the subsequent security prompt.8. Wait with further operations until the copying process has completed and the message "PROCESS FINISHED" is displayed. This may take up to 20 s per protocol. During this time the device cannot be operated. Acknowledge the completion of the copying process with [OK].
	<ol style="list-style-type: none">9. After completed copying go back to the data carrier CARD and make sure that the protocols have been copied.
	<ol style="list-style-type: none">10. Press [SELECT] again.<ul style="list-style-type: none">✓ This concludes the copying process and the [START] button becomes available again. The extraction protocol can now be started.<p>Note: Only remove the USB stick after the device has been switched off. Otherwise the USB stick may be damaged.</p>

6.3.4 Checking and executing individual device functions with Tools

Individual device functions can be executed in the TOOLS menu. Using these tools, the filter tips can e.g. be emptied and removed from the device after aborting an extraction protocol.

	<p>1. In the start window press the button [TOOLS].</p>
	<p>2. Select the tool for a device function and press [START].</p>
	<p>The test run is documented on screen (in this example the magnet test tool).</p>

A sample tray must be in the device to execute the tools. If this is not the case when a tool is started, a prompt to insert the tray is automatically displayed.

The following tools have been integrated into the program:

Tool	Function
AUTOCALIBRATION	Adjusting the sample tray position for correct tip removal
EMPTYING TIPS (IN CAVITY 3)	Emergency emptying of strips and plates during protocol abortion into the 3rd cavity to discharge fluid from the tips in a controlled manner. The sample tray must be populated with corresponding strips and plates.
HEAT TEST	Control of the heating function
INITIALIZATION	Initialization of the InnuPure C16 after protocol abortion or after an error

MAGNET TEST	Control of the positioning of the magnet unit
TRANSPORT LOCK (IN TIPLINE 1)	Arresting the transport lock for minor transports (moving within the lab)
TRAY OUT	Release of the sample tray from the device
WASTE TIPS (IN CAVITY 3)	Ejection of the filter tips into the 3rd cavity after a protocol abortion. The sample tray must be populated with corresponding strips and plates.

6.3.5 Work with user ID management



IMPORTANT

A user with administration rights has been configured in as default:

Password: IPC16

User name: Administrator

User rights

Within the user administration the rights can be assigned at two levels:



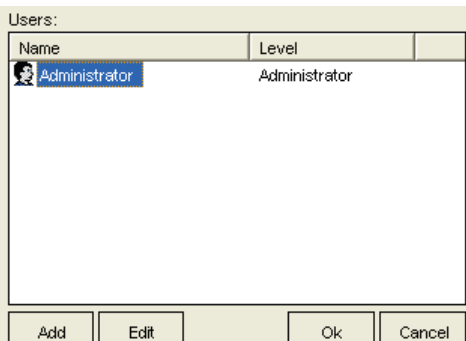
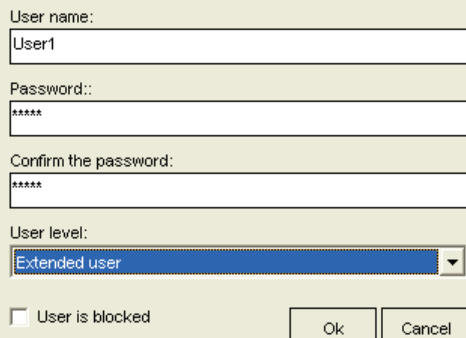
	Administrator	Extended user
Starting a protocol	+	+
Starting a tool	+	+
Copying / moving / deleting protocols	+	-
Creating/deleting users	+	-
Changing user login	+	+
Exiting the control program of the InnuPure C16	+	-
Control of [LOGIN AT START]	+	-

Note:

Service settings are only accessible to service personnel with appropriate access rights.

Creating/modifying a user profile

The creation of a user profile or modification of an existing profile takes place via the SETTINGS menu. The password can be changed in an existing user profile. An administrator may also block the profile of an "extended user".

	<p>1. In the start window press the button [SETTINGS].</p>
	<p>2. Select the menu item [USER MANAGEMENT].</p>
	<p>3. Press [ADD] to create a new user profile or [EDIT] to modify an existing profile (e.g. to change the password).</p>
	<p>4. Enter the following data for a new user profile:</p> <ul style="list-style-type: none"> – USER NAME (user administration) – Password and password confirmation – Selection of the user level (USER LEVEL) <p>Note: By enabling the checkbox USER IS BLOCKED an administrator can block an "extended user" profile.</p>
<p>5. Acknowledge the entries with [OK] and exit the next screen also with [OK].</p>	

Switching user login at Start on/off

The automatic user login at the start of the InnuPure C16 is a program default. It can only be disabled by a user with administrator rights. The function for disabling/enabling is accessed via the [MENU] button in the top left corner of the start screen.

1. Press the [MENU] button.

2. In the menu displayed disable the function LOGIN AT START if no login prompt is to be shown when starting the InnuPure C16.

At the next program start the last logged in user is automatically logged in.

Logging in a different user

Whilst working in the program of the InnuPure C16 a different user can be logged in. The change of login is affected via the [MENU] button in the top left corner of the start screen.

1. Press the [MENU] button.
2. Select the menu item NEW LOGIN.
3. Enter the new user name and corresponding password and confirm your entries with [OK].

6.3.6 Switching the interior light on and enabling the touch sensor

The interior of the InnuPure C16 is illuminated during the processing of an extraction protocol. However, the illumination can also be switched on and off separately. During the processing of an extraction protocol the touch sensor is disabled to prevent the device from accidentally being switched off. If a running protocol is aborted using the [STOP] button or on account of an error, the touch sensor remains disabled and must be switched back on if required.

1. On the start screen press the button [SETTINGS].
2. Select the menu item [DEVICE COMMANDS].
3. Press the [LIGHT ON/OFF] button to switch the light on and back off.
4. To re-enable the touch sensor press the button [TOUCH SENSOR ON].

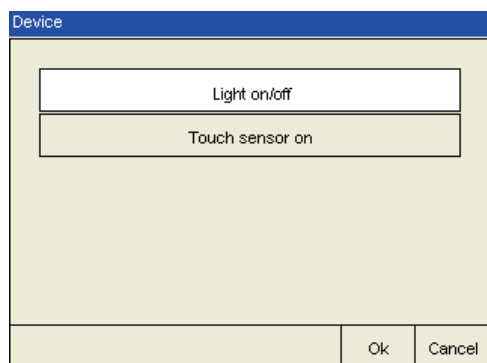



Figure 10 Switching the interior light on / enabling the touch sensor

6.3.7 Configuring the time

The date and time of the InnuPure C16 are configured via a clock symbol in the top right corner of the start screen.

1. Press the clock symbol  in the start window.
2. Set the date and time and confirm the entries with [OK].

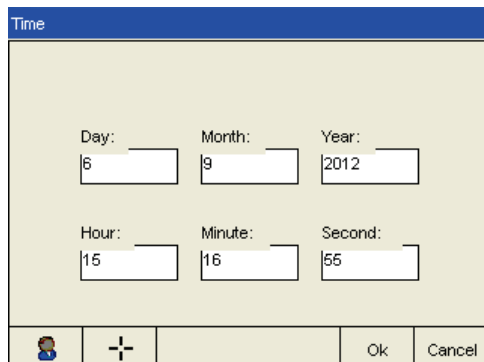


Figure 11 Window for configuring date and time

7 Fault removal



IMPORTANT

If faults cannot be remedied by the customer, the Analytik Jena AG service department or agency must always be informed. This also applies for the repeated occurrence of individual faults.

In case of an error message perform the following steps:

- ☐ Acknowledge the error message with [OK].
- ☐ Switch the device off and back on.
- ☐ Wait until the beep sounds to signal the completion of the initialization.
- ☐ Remove any sample residue and filter tips left behind with the tool [EMPTYING TIPS (IN CAVITY 3)] and [WASTE TIPS (IN CAVITY 3)].

If this does not fix the error or the problem reoccurs, make a note of the error message and notify the service department of Analytik Jena AG.

7.1 Error messages

Possible error message	Meaning
Command incorrect	Internal command incorrect/incomplete
Slave response incorrect	Response from 2nd control incorrect/incomplete
Calibrating error Z-axis Calibrating error Y-axis	Error during the calibration of a drive axis
Positioning error Y-axis Positioning error Z-axis Positioning error P-axis Positioning error M-axis Positioning error ejector	Error during the positioning of a drive axis
Initialization error Y-axis Initialization error Z-axis Initialization error P-axis Initialization error M-axis Initialization error ejector	Error during the initialization of a drive axis
Reading default values failed Writing default values failed	Reading or writing of the default values failed
Reading calibrate values failed Writing calibrate values failed	Reading or writing of the calibration values failed
Runtime Error	Undefined error
Maxdiff value Y1-axis exceeded Maxdiff value Y2-axis exceeded Maxdiff value Z-axis exceeded Maxdiff value P1-axis exceeded Maxdiff value M-axis exceeded	Maximum permissible position deviation exceeded in a drive axis

Maxforce value Y1-axis exceeded Maxforce value Y2-axis exceeded Maxforce value Z-axis exceeded Maxforce value P1-axis exceeded Maxforce value M-axis exceeded	Permissible maximum current of a drive axis exceeded
Difference temperature sensor values too high	Max. permissible difference between the two temperature sensor values exceeded
Plausibility error temperature sensor left Plausibility error temperature sensor right	Temperature value of the left or right temperature sensor not plausible
Error heating system	Error in the heating system
Timeout by communication	Timeout during the execution of an internal command of the user interface
Device Error!	Generally displayed after all error messages in an additional message window.

7.2 Notes on preventing errors

Observe the following notes to prevent errors during the daily routine:

1. After switching on the device automatically moves to its start position. Any fluids still present in the tips after an abortion/power failure are not discharged in the process. In this case the fluid can be discharged using the tool [EMPTYING TIPS] in the TOOLS menu (see section "Checking and executing individual device functions with Tools" p. 35).
2. Wait approx. 30 s after switching on the InnuPure C16 for the device initialization to be completed, which is indicated by a beeping sound. Only then may the HID-Pro 320 be operated or the sample tray be moved into the device. Otherwise, program faults may result.
3. Before starting an extraction protocol or a device function make sure that no consumables from previous processes have remained in the device. Remove the consumables using the tools [EMPTYING TIPS], [WASTE TIPS] and [TRAY OUT] in the TOOLS menu.
4. If tips are present at the cones, no protocol may be started and the tools [AUTOCALIBRATION] and [TRANSPORT LOCK] may not be executed. Otherwise the tips might be damaged and the device be calibrated incorrectly.
5. The InnuPure C16 can be switched off at any time from mains switch at the equipment backplate, even whilst an extraction protocol is running. Switching off using the touch sensor is only possible if this has been enabled.
6. To protect against accidentally switching the device off, the touch sensor function is disabled between calibration and the completion of the protocol when protocols / tools are run during which fluids are moved. Since in the case of an aborted protocol after calibration the touch sensor function is not re-enabled automatically, this can be performed by the user via [SETTINGS] | [DEVICE COMMANDS] | [TOUCH SENSOR ON].
7. During the execution of extraction protocols or device functions the process can be aborted using the [STOP] button. However, the last sent command is still completed. This has the following effects:

- The device does not stop immediately if a movement command is running. The last movement command is still completed. During a calibration/initialization this may take max. 30 s.
- If heating or waiting steps are running the device will only be operable again after these have completed,
 - during pure waiting / collection steps (heating inactive) up to 60 s,
 - during heated elution steps up to 100 s,
 - during drying steps up to 420 s.

However, switching off from the mains switch results in immediate abortion.

If a message is present in an overriding window, this must be edited / acknowledged prior to an abortion. Returning to the main screen of the user interface is possible after an abortion by pressing the cross symbol (top right in the window).

During the tip ejection step (applicable to all extraction protocols / tools) it is not possible to abort the protocol using the [STOP] button. The button is disabled during this step.

8. During the processing of protocols / tools the sample tray must only be inserted by the user after a prompt or only be removed after completion of the protocol even if it protrudes from the housing!
9. After switching off the device min. 5 minutes must pass before an intervention in the device is permitted. In worst cases the magnetic strip may be up to 80°C hot at the time of switching off but cools down relatively quickly to a temp. < 50 °C.
10. During the automatic pulling in of the sample tray the overcurrent protection of the tray drives may occasionally trip without an error message being issued. The sample tray stops during entry and is not initialized. The device can be re-activated by restarting any extraction protocol or device function. To only release the sample tray use the tool [TRAY OUT].

8 Maintenance and care

The InnuPure C16 is mainly maintenance-free. Care and maintenance are limited to cleaning the device, changing the fuses and installing software updates.



CAUTION!

The device cover must only be opened by the technical customer service of Analytik Jena AG or its authorized agency. Before opening the device cover disconnect the mains plug!

8.1 Cleaning the InnuPure C16



CAUTION! Danger of electric shock!

Before cleaning the device with disinfection agents, disconnect the mains plug from the connection of the InnuPure C16!

The InnuPure C16 must only be recommissioned once it is completely dry!

Clean the InnuPure as follows:

- ☐ Avoid contamination by handling sample substances with care.
- ☐ Wipe spilled samples or reagents immediately with an absorbent cloth or piece of paper.
- ☐ If the InnuPure C16 is used for the analysis of infectious material, great care must be taken, because the InnuPure C16 cannot be decontaminated as a whole device.
- ☐ Visible contamination must be removed immediately using suitable detergents, making sure that no solvent enters the inside of the device.
- ☐ The drip tray can be removed from the device for cleaning with the door open.

Caution!

The magnet heating elements must not be in the up position.

- ☐ The adapters for accepting the reagent strips can be autoclaved and are also suitable for dip and spray disinfection.
- ☐ The sample tray is also suitable for dip and spray disinfectant
- ☐ As a possible disinfection agent we recommend

Decosept AF disinfectant spray Fa. Dr. Schuhmacher GmbH
 Meliseptol HBV cloths by B. Braun
- ☐ If the InnuPure C16 has to be sent to Analytik Jena AG for service after infectious material has been processed with it, a prior decontamination must be carried out and documented (see documents in the product folder).

8.2 Changing fuses

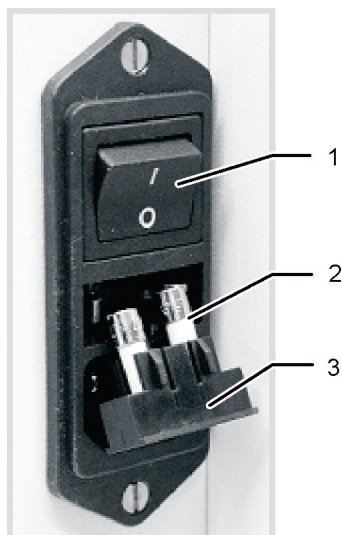


CAUTION! Electric shock!

Disconnect the mains plug before changing fuses!

If the fuses in the heat exchanger are faulty you can replace them.

1. Switch off the InnuPure C16 and disconnect the mains plug from the connection of the InnuPure C16.
2. Open the fuse holder by pulling its cover.
3. Replace the faulty mains fuses. Use the following fuses:
2 x T 4A; 250 V
4. Close the fuse holder.
5. Connect the InnuPure C16 to the mains.
6. Switch on the InnuPure C16.



- | | |
|---|--------------|
| 1 | Mains switch |
| 2 | Fuses |
| 3 | Fuse holder |

Figure 12 Open fuse holder

8.3 Software update

The software update is sent by email. Observe the instructions for decompressing and, where applicable, renaming the files. Save the files in accordance with the instruction on a USB stick in the directory "IPC16". The following files must then be in this folder:

- ☐ "appfile.txt" (designates the file to be updated)
- ☐ "IPC16.exe" (new software version = the actual update)
- ☐ "IPCupd.exe" (tool executing the update)

The steps required for an update are described below:

1. Switch on the InnuPure C16.

2. Wait for the device to initialize (beeping sound) and log in if necessary.
3. Insert the USB stick into the USB port at the right-hand side of the HID-Pro 320
4. In the main menu press the button [SETTINGS].
5. Press [UPDATE].
6. In the UPDATE menu press the [UPDATE] button to start the UPDATE TOOL.
7. In the main menu of the UPDATE TOOL press the [UPDATE SOFTWARE] button.
8. In the menu SOFTWARE UPDATE press the [UPDATE] button.
 - ✓ **The update is executed automatically and is complete as soon as the [Close] is displayed again (after approx. 3 – 4 s).**
9. Press [CLOSE] to exit the SOFTWARE UPDATE menu.
10. Exit the UPDATE TOOL with [EXIT].
11. Switch the device off and back on to perform a re-initialization.
 - ✓ **The InnuPure C16 is ready for operation again.**

Note

The software update is not tied to user rights! It can be executed by any user!

9 Transport and storage

9.1 Transport

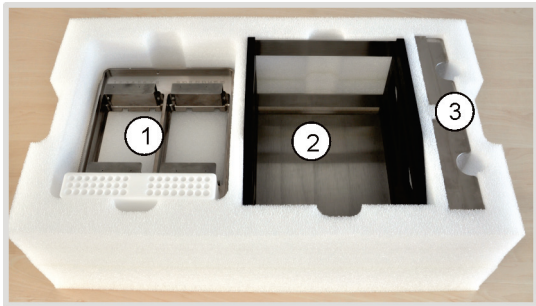

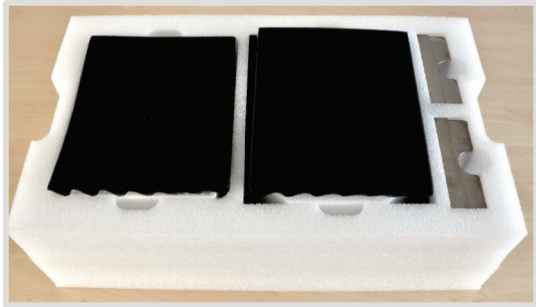
9.1.1 Preparing the device for transport








ATTENTION!

For packaging only use the transport packaging recommended by AJ. Only this provides optimum protection of the InnuPure C16 against transport damage.

Pack the InnuPure C16 as follows:

<ol style="list-style-type: none"> 1. Remove remaining consumables from the InnuPure C16. 2. Switch off the device and disconnect the mains plug from the InnuPure C16. 	
	<ol style="list-style-type: none"> 3. Insert the sample tray (1), the priming station (2) and the adapters for reagent strips (3) (optional) into the spaces in the accessory box provided.
	<ol style="list-style-type: none"> 4. Place the foam cover onto the sample tray and place the insert into the priming station. 5. Place the HID-Pro 320 into the opening of the insert for the priming station.
	<ol style="list-style-type: none"> 6. Cover the openings of the sample tray and the priming station with the black foam mats.

	<p>7. Place the foam frame for the device base onto the floor of the packaging.</p>
	<p>8. Wrap the Innupure C16 into the plastic bag to protect it against scratching and place it into the packaging.</p> <p> CAUTION! For reasons of safety 2 persons are required to lift the device and must position themselves on both sides of the equipment. Grip the device firmly with both hands at the lower end, lifting it simultaneously. Make sure the door is closed. Do not hold from the door area.</p>
	<p>9. Slide the second foam frame for the device top onto the Innupure C16.</p>
	<p>10. Place the accessory packaging between the struts of the foam frame (for better visibility shown without cover in the photo).</p>



11. Cover the accessory insert with the white foam cover and place the cardboard cover on top of it.
12. Place the mains plug onto the cardboard cover as shown.

Note:

If you send the InnuPure C16 to Analytik Jena AG, complete the decontamination description and place it together with an error description into the cardbox.

9.1.2 Transport notes

Observe the safety instructions in chapter "Safety instructions, transport and installation" p. 11. Transport the InnuPure C16 very carefully to prevent damage from impact or vibration. The InnuPure C16 should be transported in such a way that major temperature fluctuations are avoided and the formation of condensate is thus prevented.

9.1.3 Moving the device in the laboratory



CAUTION

Unintentional dropping of the InnuPure C16 creates a risk of injury and damage to the module!

Move the InnuPure C16 with great care! 2 persons are required to lift and carry the device!

When moving the InnuPure C16 in the laboratory observe the following:

- ☐ Insert the sample tray and start the tool [TRANSPORTATION LOCK IN TIPLINE 1]. This moves the cones into the tip row 1 of the sample tray and arrests the axes for a short transport.
- ☐ Switch off the device and disconnect the mains connection. Remove the HID Pro 320 from the device.
- ☐ To prevent health damage the following must be observed when moving the device in the laboratory (lifting and carrying):
 - For reasons of safety 2 persons are required to transport the device and must position themselves on both sides of the equipment.
 - Because the device does not have carrying handles, grip the device firmly with both hands at the lower device end. Make sure the doors are closed before lifting the device simultaneously.
 - Observe the guide values and adhere to the legally mandated limits for lifting and carrying without auxiliary means!
- ☐ For the setup at the new location observe the notes in section "Site requirements" p. 22.

9.2 Storage



CAUTION

Environmental influences and condensate formation can destroy individual components of the device!

The device must only be stored in air-conditioned rooms. The atmosphere must be low in dust and free from aggressive vapors.

If the device is not installed immediately after delivery or not required for prolonged periods, it should be stored in its original packaging. A suitable desiccant should be added to the equipment to prevent damage from moisture.

The following storage conditions must be met:

- ☐ Temperature range: -10 – 55 °C
- ☐ Max. humidity: max. 80 % (use desiccant)

10 Disposal



ENVIRONMENTAL PROTECTION

At the end of its service life the InnuPure C16 and all its electronic components must be disposed of in accordance with the applicable regulations as electronic waste.

EG Konformitätserklärung EC Declaration of Conformity

Name und Anschrift des Herstellers:
Name and address of the manufacturer:

CyBio AG

Göschwitzer Straße 40
D-07745 Jena

Hiermit erklären wir, dass das nachstehend beschriebene Produkt
Herewith we declare, that the product described below

InnuPure C16
30-7115-001-26

Seriennummer:

allen einschlägigen Bestimmungen der Maschinenrichtlinie 2006/42/EG entspricht.
Das Produkt entspricht zusätzlich den Bestimmungen der europäischen Richtlinien 2006/95/EG über elektrische Betriebsmittel und 2004/108/EG über elektromagnetische Verträglichkeit.

*is complying with all essential requirements of the Machinery Directive 2006/42/EC.
In addition the product is in conformity with the EC Directives 2006/95/EC relating to electrical equipment and 2004/108/EC relating to electromagnetic compatibility.*


Angewandte harmonisierte Normen:
Harmonized Standards used:

EN ISO 12100: 03/2011	Sicherheit von Maschinen - Allgemeine Gestaltungsgrundsätze - Risikobeurteilung und Risikominderung	<i>Safety of Machinery - General principles for design - Risk assessment and risk reduction</i>
EN 61010-1: 07/2011	Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte	<i>Safety requirements for electrical equipment for measurement, control and laboratory use</i>
EN 61326-1: 10/2006	Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV Anforderungen - Allgemeine Anforderungen	<i>Electrical equipment for measurement, control and laboratory use - EMC requirements - General requirements</i>

Bevollmächtigter für die Zusammenstellung der relevanten technischen Unterlagen:
The person authorized to compile the relevant technical documentation:

Jochen Eckardt, Göschwitzer Str. 40, D-07745 Jena

Jena, 5.9.2012


Steffen Kammel, (Leiter Produktion)
(Manager Production)

Diese Erklärung bezieht sich nur auf das Produkt in dem Zustand, in dem es in Verkehr gebracht wurde; vom Endnutzer nachträglich angebrachte Teile und/oder nachträglich vorgenommene Eingriffe bleiben unberücksichtigt. Die Erklärung verliert ihre Gültigkeit, wenn das Produkt ohne Zustimmung umgebaut oder verändert wird.

This declaration relates exclusively to the product in the state in which it was placed on the market, and excludes components which are added and/or operations carried out subsequently by the final user. The declaration is no more valid, if the product is modified without agreement.